EXHIBIT 7

From: <u>Sudhakar Vidiyala</u>
To: <u>Vasu Sabbella</u>

Subject: FW: DEA Request for Additional Information for 2023 application submitted by Ascent Pharmaceuticals

RA0448503

Date: Monday, September 25, 2023 9:41:50 AM

Attachments: <u>image001.jpg</u>

Thank You,

Sudhakar Vidiyala

From: Strait, Matthew J. [mailto: Matthew.J.Strait@dea.gov]

Sent: Thursday, October 27, 2022 4:37 PM

To: Sudhakar Vidiyala <<u>sudhakar@ascentpharm.com</u>>

Cc: Harper-Avilla, Stacy < Stacy.Harper-Avilla@dea.gov>; Treasure-McDowell, Susan < Susan.Treasure-

McDowell@dea.gov>

Subject: DEA Request for Additional Information for 2023 application submitted by Ascent

Pharmaceuticals RA0448503

Mr. Vidiyala:

Based on ongoing discussions with DEA Field Investigators, DEA continues to seek information from Ascent Pharmaceuticals regarding the accuracy of its records relating to the manufacture, inventory and use of schedule II controlled substances. This information is relevant to your quota requests because it may be helpful in detecting or preventing diversion. *See* 21 C.F.R. 1303.12(b). Your applications remain under review at this time.

Sincerely,
Matthew Strait
Deputy Assistant Administrator
DEA Diversion Control Division

From: Sudhakar Vidiyala < sudhakar@ascentpharm.com >

Sent: Wednesday, October 26, 2022 10:04 AM **To:** Strait, Matthew J. < Matthew.J.Strait@dea.gov>

Cc: Harper-Avilla, Stacy < Stacy. Harper-Avilla@dea.gov >; Treasure-McDowell, Susan < Susan. Treasure-McDowell@dea.gov >

Subject: [EXTERNAL] RE: [EXTERNAL] RE: DEA Request for Additional Information for 2023 application submitted by Ascent Pharmaceuticals RA0448503

Dear Matthew,

Can you please update me on the status of our application as we are approaching end of the calendar year. We lost more than 40 employees so far without work and will be loosing more people in next few weeks if we don't provide work. I have been requesting a call or in person meeting to go

over on the issues, but unfortunately you never responded to those requests. Please call me or arrange in person meeting to resolve the issues. I appreciate your prompt response on my request

Thank You,

Sudhakar Vidiyala

From: Sudhakar Vidiyala [mailto:<u>sudhakar@ascentpharm.com</u>]

Sent: Friday, October 21, 2022 9:02 AM

To: 'Strait, Matthew J.' < <u>Matthew.J.Strait@dea.gov</u>>

Cc: 'Harper-Avilla, Stacy' < Stacy.Harper-Avilla@dea.gov">Stacy.Harper-Avilla@dea.gov

<Susan.Treasure-McDowell@dea.gov>

Subject: FW: [EXTERNAL] RE: DEA Request for Additional Information for 2023 application submitted

by Ascent Pharmaceuticals RA0448503

Dear Matthew,

Please refer to the following facts to consider to issue quota for 2022:

- Based on our forecast / usage, DEA issued quota to API suppliers for Amphetamines and Methylphenidate APIs
- They manufactured API for our need and sitting with API since few months
- Since Ascent doesn't have quota, they are waiting for our quota as they manufactured based on our forecast and usage. Please note that they cannot supply API to other manufacturer as the API supplier should be qualified and get approved by FDA
- In this case, they do not have other manufacturer qualified, in result they cannot supply to others
- If we have quota, we can resolve at some level of drug shortage situation as quickly as possible for both Amphetamine and methylphenidate products
- Please note that we developed OROS Technology for Concerta product similar to brand technology, is being well accepted by patients unlike other majority generic players. This is one of the reason to have considerable market share for Concerta
- We also understand Opiod crisis but our usage of both Oxycodone and Hydrocodone are negligible compared to aggregate quota approved by DEA.
- We have been cooperative with DEA on providing any information being requested within short period of time

We request you to consider above facts and take decestion as quickly as possible. Thank You,

Sudhakar Vidiyala

From: Venkat Jayaraman [mailto:venkat@ascentpharm.com]

Sent: Friday, October 21, 2022 7:28 AM

To: Sudhakar Vidiyala <<u>sudhakar@ascentpharm.com</u>>

Cc: Vasu Sabbella <<u>vasu@ascentpharm.com</u>>; Meghana Vidiyala <<u>meghana@ascentpharm.com</u>>

Subject: FW: [EXTERNAL] RE: DEA Request for Additional Information for 2023 application submitted

by Ascent Pharmaceuticals RA0448503

Dear Sir,

Good Morning. Below response received for 2022 quota request.

Thanks
Best Regards
Venkat.J

From: Treasure-McDowell, Susan [mailto:<u>Susan.Treasure-McDowell@dea.gov]</u>

Sent: Friday, October 21, 2022 7:18 AM

To: Venkat Jayaraman < <u>venkat@ascentpharm.com</u>>

Subject: RE: [EXTERNAL] RE: DEA Request for Additional Information for 2023 application submitted

by Ascent Pharmaceuticals RA0448503

Mr. Jayaraman,

Your firm's 2022 pending quotas for the listed request ID are still being processed and reviewed. As stated in the July 1, 2022 letter from DEA, substances used to manufacture ADHD medications are undergoing extra investigation during the quota review process. The information your firm and others have provided is being reviewed in effort to evaluate the ADHD medication manufacturing space. You may contact Deputy Assistant Administrator Matthew J. Strait, Office of Diversion Control Regulatory, at matthew.j.strait@dea.gov with comments, questions or concerns.

Regards,

Susan Treasure-McDowell
Drug Science Specialist
UN Reporting and Quota Section
Diversion Control Division
Drug Enforcement Administration

From: Venkat Jayaraman <<u>venkat@ascentpharm.com</u>>

Sent: Friday, October 21, 2022 6:54 AM

To: Treasure-McDowell, Susan < <u>Susan.Treasure-McDowell@dea.gov</u>>

Subject: [EXTERNAL] RE: DEA Request for Additional Information for 2023 application submitted by

Ascent Pharmaceuticals RA0448503

Hi Susan Treasure-McDowell,

Good Morning. We acknowledge the receipt of your email and provide the response within the timeline.

Can you please provide an update on pending Quota for the rest of the year 2022 for the below mentioned request Id.

S.No	Material Name	Quota Request ID
1	D,L Amphetamine	148756
2	D Amphetamine	148755
3	Hydrocodone Hcl	148876
4	Oxycodone Hcl	148761
5	Methylphenidate	148877

Thanks

Best Regards

Venkatasubramanian Jayaraman

Director- Head Quality and

DEA Compliance, Security.



Ascent Pharmaceuticals, Inc.

400 South Technology Drive

Central Islip, NY 11722 USA

Phone: (631) 881-4614 Ex. 1405

Fax: (631) 881-4615

E-Mail: venkat@ascentpharm.com

Cell: (631)-617-7333

From: Treasure-McDowell, Susan [mailto: Susan. Treasure-McDowell@dea.gov]

Sent: Wednesday, October 19, 2022 4:28 PM

To: VENKAT@ASCENTPHARM.COM

Subject: DEA Request for Additional Information for 2023 application submitted by Ascent

Pharmaceuticals RA0448503

Dear registrant,

This email is in reference to the 2023 application submitted for procurement quota by Ascent Pharmaceuticals, Inc. RA0448503. In order to continue processing your application, the following information is needed for:

- 1. D,L-AMPHETAMINE
- 2. D-AMPHETAMINE (FOR SALE)
- 3. METHYLPHENIDATE (FOR SALE)
- 4. DEXMETHYLPHENIDATE (FOR SALE)
- 5. OXYCODONE (FOR SALE)
- 6. HYDROCODONE (FOR SALE)

Please provide your 2022 Customer List with (YTD) year to date sales aggregated by DEA number (in excel format). The customer lists should have the DEA registration shown ONCE in the entire

document and the aggregated total sold to that DEA Number in gram base or kilogram base.

Please respond to this email within 10 business days. Your request cannot be processed without this information. If the requested information is not received within 10 Business days, your request will not be processed and a denial letter will be issued.

Regards,

Drug Science Specialist UN Reporting and Quota Section Diversion Control Division Drug Enforcement Administration

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